

**HTA/Payer Real World Data Context to support  
Outcomes Based Managed Entry Agreements (OBMEA)/  
Conditional Reimbursement with Data Collection**

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Role	Pharmacoeconomist
Country	Finland
Date of completion	22 May 2022
Health System Organisation	The responsibility for organising public health care and social welfare will be transferred from municipalities to wellbeing services counties from 2023.
Health System Funding	<ul style="list-style-type: none"> <li>- Multi-channel financing model</li> <li>- Different managed entry process for reimbursed outpatient medicines, hospital only medicines, national vaccination program and pharmaceuticals for certain communicable diseases</li> <li>- The costs of highly innovative technologies that will be administrated in hospitals are included in the patient charge. In Finland, the patient’s municipality of residence pays for the hospitalisation. (The responsibility for organising public health care and social welfare will be transferred from municipalities to wellbeing services counties from 2023).</li> </ul>
1. Does each patient in your health system have a unique patient id that enables data linkage?	<p>Yes</p> <p>A personal identity code is a number sequence with 11 characters, based on date of birth and gender. Individuals will need their personal identity code in their contact with, for instance, public authorities, banks and employers. Each personal identity code is unique.</p>
2. Can the prescribing record be linked with the indication?	All prescriptions are issued or signed electronically by doctors. Prescriptions are saved in the Prescription Centre, which is a centralised database for prescription data in the Kanta service. Currently, indication is in free text in e-prescriptions.

3. What sources and types of data could be used in your health system for conditional reimbursement purposes or OBMEA (e.g. to determine clinical effectiveness or inform economic evaluations)?

This will vary by indication and whether the treatment is reimbursed by the Social Insurance Institution and used in outpatient care, or administered in hospital setting. In the outpatient setting different datasets will need to be combined, and availability of outcome data will be the issue + the level of detail needed for the indication data.

In hospital setting, regional data lake, for example, could be a source of electronic health records (EHR) and other data. National health care quality registers could also be a source of data in the future. <https://thl.fi/en/web/social-welfare-and-health-care-reform/health-and-social-services-system-performance-assessment/national-health-care-quality-registers>.

In our national architecture for secondary use of health care data, the main data sources are classified as follows:

- Public and private service providers of social welfare and health care (e.g. EHRs)
- [Kanta-services](#). This is national digital services for the social welfare and healthcare sector. Kanta Services are e.g. My Kanta Pages, e-prescription service and Patient Data Repository.
- Other national social and healthcare data sources (e.g. genom data)
- Other (regional) social and healthcare data source (e.g. biobanks)
- National registers and statistics
- Other national data sources (e.g. reimbursement data from Social Insurance Institution)

This architecture is a little outdated, and we're just starting to update it. But at the current point in time, provider data is the most important source of OBMEA data. In the future, the Kanta-service might be a source as well.

4. Do data catalogues exist that include descriptions of the content (meta-data) of distributed data sources, which could support discoverability of data for HTA/Payer purposes?

Yes.  
The data descriptions are available in a Data Catalogue developed jointly by the Finnish Institute for Health and Welfare, the Finnish Social Science Data Archive, and The Finnish Innovation Fund Sitra. However, the work is still in process.

5. Are there any standards or systems in place to judge data quality?

In development [https://www.stat.fi/org/tilastokeskus/vuosiohjelma\\_en/data-quality-framework-project-increases-use-of-data.html](https://www.stat.fi/org/tilastokeskus/vuosiohjelma_en/data-quality-framework-project-increases-use-of-data.html)

6. Are there any tools or processes to appraise data suitability for OBMEA/conditional reimbursement purposes, such as the EUnetHTA REQuest Tool for registries?

Not to my knowledge.

7. Describe “Secure Operating Environments” or “Trusted Research Environments” that exist within clear governance processes to enable access for approved purposes to one or more data sources that could potentially be used for HTA/Payer purposes.

Kapseli remote access system is Findata’s secure operating environment for processing data in accordance with the data permits. Kapseli is accessed remotely by logging in through a web browser.

The analysis of data at individual level is only permitted in environments that meet the requirements of the the Act on Secondary Use of Data, as of 1 May 2022. The requirements require the same level of information security as is required for Findata’s own operating environment.

<https://findata.fi/en/kapseli/>

<https://findata.fi/en/kapseli/regulation-on-secure-operating-environments/>

<https://www.valvira.fi/web/en/healthcare/social-welfare-and-healthcare-data-systems/secure-operating-environments-under-the-act-on-the-secondary-use-of-health-and-social-data>

8. How is access to data governed (e.g. legislation, data permits, register of uses )? Are there differences in governance between national and regional datasets?

Findata is a Health and Social Data Permit Authority, a one-stop shop for the secondary use of health and social data. Findata offers services

- for those needing data (customers) and
- for those controlling data (controllers)
- All Findata services relate to the secondary use of health and social data.

Findata can assist in situations where

- data from several different controllers is being combined,
- the register data originates from private social welfare and health care service providers
- or the data is stored in Kanta services. Findata will process applications related to medical record data in the Kanta services from the beginning of 2021, applications related to e-prescription data can be processed already now.

A separate law has been laid down on the secondary use of health and social data (Act on the Secondary Use of Health and Social Data).

Source: <https://findata.fi/en/>

<p>9. What other information do we need to know about data governance and accessibility in your health system?</p>
<p><b>NATIONAL/REGIONAL SETUP</b></p> <ul style="list-style-type: none"> <li>- Different managed entry process for reimbursed outpatient medicines, hospital only medicines, national vaccination program and pharmaceuticals for certain communicable diseases</li> </ul>
<p>10. Is there a precedent for national health system data to be used in OBMEA/conditional reimbursement? If yes, describe any supporting legislation or processes. If no, identify key challenges.</p>
<p>This is not public information.</p>
<p>11. Describe any collaboration your country/region is undertaking to enable health data access across borders?</p>
<p>Joint Action for the European Health Data Space – TEHDAS is co-ordinated by Sitra (the Finnish Innovation Fund). <a href="https://tehdas.eu/">https://tehdas.eu/</a></p>
<p>12. Any other comments?</p>
<p>13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.</p>
<p><b>CURRENT REVIEWS/REFORMS</b></p> <ul style="list-style-type: none"> <li>- Health and social services reform (<a href="https://soteuudistus.fi/en/frontpage">https://soteuudistus.fi/en/frontpage</a> )</li> <li>- Changes in financial management of health care (The aim to simplify our complex multichannel financing system is part of Programme of Prime Minister Sanna Marin’s Government).</li> <li>- Reform on pharmaceutical matters (<a href="#">&gt;link</a>)</li> </ul>